OBJ_DOKU-187952-003.fm Seite 1 Montag, 14. April 2014 10:24 10

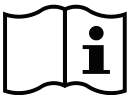
Notes on use

usa

ERBE NESSY ®Omega Plates

Disposable split return electrodes

20193-084



ERBE

OBJ_DOKU-187952-003.fm Seite 2 Montag, 14. April 2014 10:24 10

Table of Contents

IMPORTANT! **3**
1 Normal Use **3**
2 Safety Instructions **3**
3 Product benefits **4**
4 Explanation of packaging symbols **5**
5 How to Use **5**
5.1 Opening the packaging 5
5.2 Check the expiration date 6
5.3 Pull-off label for documentation purposes 6
5.4 Selecting a suitable application site 6
5.5 Preparing the application site. 7
5.6 Attaching the return electrode. 7
5.7 Reducing the risk of accidental tissue damage 7
5.8 Repositioning the patient during surgery 8
5.9 Removing the return electrode. 8
6 Monitoring of the return electrode by the electro-surgical unit **8**

OBJ_DOKU-187952-003.fm Seite 3 Montag, 14. April 2014 10:24 10

IMPORTANT!

Please read all information carefully.

These notes on use do not replace the user manual of the electrosurgical unit (ESU) used! Read the user manual of the electrosurgical unit and ask ERBE or your distributor in case of doubt!

Caution! Federal law (USA) restricts this device to sale by or on the order of a physician!

1 Normal Use

These return electrodes are intended to be used for dispersing and as applicable monitoring High Frequency (HF) current during electrosurgical procedures when connected to an electrosurgical unit (ESU) and applied to the skin of the patient.

Split return electrodes should be used with electrosurgical units that have a safety monitoring system.

The return electrodes are to be connected to the electrosurgical units specified in the declaration of conformity (of the return electrodes) only.

2 Safety Instructions

WARNING!

This product may only be used by medical personnel who have been trained per these instructions.

Check the insulation on the return electrode, cable, and plug for damage before use.

Never use damaged return electrodes, cables, or plugs.

ERBE recommends that the product not be reprocessed after use. Reprocessing can affect material properties and/or product function making its Normal Use no longer possible. Concerns involve:

- Components/connections that are damaged by high temperatures (e.g. in the autoclave).

ERBE Elektromedizin expressly warns against modifying or cutting the return electrode. Any modification exempts ERBE Elektromedizin from any and all liability.

3 Product benefits

- An equipotential ring distributes the HF current and thereby the heat to both halves of the return electrode.
- Due to its symmetry, the return electrode can be oriented to the patient any way that is desired.
- The contact gel overlaps all aluminum edges which reduces the heating of the edges of the return electrode. The contact gel also protects against fluids from penetrating under the return electrode.
- The return electrode's surface is flexible and skin-friendly.
- Pull-off label for documentation purposes.
- Pull-off tab to easily remove the return electrode from the protective film and skin.
- The product is suitable for latex allergy sufferers. It contains no latex and no typical natural rubber additives (i.e. the return electrodes cannot trigger any allergic reactions to latex).

4 Explanation of packaging symbols

The following are some atypical symbols which may be encountered with a return electrode. Please familiarize yourself with their meaning.

The product is suitable for latex allergy sufferers. It contains no latex and no typical natural rubber additives (i.e. the return electrodes cannot trigger any allergic reactions to latex).

The product can be used up to 14 days after opening the sealed packaging. Do not use the product after this period has lapsed.

5 How to Use

WARNING!

Return electrodes are part of a safety system. The following instructions for use are therefore also safety instructions. They must be strictly observed to prevent patients from being burned.

5.1 Opening the packaging

The return electrodes are not packaged sterile. To open, tear off the strip on the dispenser carton and open the pouch. Once the pouch has been opened, use the return electrodes within 14 days. Always keep unused return electrodes in the pouch. Reclose by folding over.

The film protects the return electrode from drying out. Remove the protective film right before application, otherwise the conductive hydrogel will dry out and the return electrode will no longer be usable.

OBJ_DOKU-187952-003.fm Seite 6 Montag, 14. April 2014 10:24 10

5.2 Check the expiration date

An expiration date is indicated on the return electrode packaging. Never use return electrodes after the expiration date.

5.3 Pull-off label for documentation purposes

The pull-off and reattachable label can be used for documentation purposes (e.g. for the patient file, anesthesia record, etc.).

5.4 Selecting a suitable application site

Apply the return electrode to an appropriate vascularized area of muscle mass, as close as possible to the surgical site, following A.O.R.N. ("Association of Operating Room Nurses") recommended practices. In any case the application site must be on an intact skin surface.

Activation of the electrosurgical unit may affect the performance of active implants (e.g. pacemakers, internal defibrillators etc.) or damage them. In the case of patients having active implants, consult the manufacturer of the implant or the competent department of your hospital prior to performing surgery. Do not position the return electrode near pacemakers, internal defibrillators, or other active implants.

The return electrode should be closer to the surgical site than ECG electrodes.

The return electrode must not be applied on or over the following locations:

- on hair
- on scars
- on inflamed skin

- on bony parts of the body
- over metal implants
- over severely adipose subcutaneous tissue
- over sacrum, hip, buttocks, shoulder blade

5.5 Preparing the application site

Shave the selected skin surface. Clean (e.g. remove any lotions, etc.) and dry the skin surface thoroughly.

5.6 Attaching the return electrode

Remove the protective film from the return electrode. Ensure that the entire surface of the return electrode is applied on the skin of the patient. Use light pressure to apply the electrode, thereby ensuring good contact of the entire adhesive surface with the skin. Make sure that there are no bubbles or folds between the skin and return electrode. Do not use contact gel.

For return electrodes without an integrated cable, use a matching ERBE connection cable (order number, see ERBE accessories catalog). Insert the contact tab of the return electrode completely into the connecting clamp. The contact tab must not touch the patient's skin because if it is in contact with the patient's skin during use a burn may occur.

Do not reapply or move a return electrode that has already been applied.

5.7 Reducing the risk of accidental tissue damage

When using the electrosurgical unit avoid lengthy activations. The temperature increases under the return electrode with lengthy and continuous activations. The patient is at risk of accidental tissue damage. In this case, make sure that there are sufficient cooling times between activations.

The lowest possible settings of the electrosurgical unit should be used to achieve the desired clinical outcome. Nonetheless prior to increasing the electrosurgical unit's power and/or effect settings, ensure that the return electrode has been correctly applied to the patient with good skin contact and verify that the connection to the electrosurgical unit is secure/intact.

5.8 Repositioning the patient during surgery

Ensure that the return electrode does not become detached from the patient's skin or shears the skin when repositioning the patient. Manually reinforce the pad when moving the patient.

5.9 Removing the return electrode

To avoid injuries to the patient's skin, peel the return electrode off the skin carefully by pulling on the tab. Never use the cable to remove the return electrode.

6 Monitoring of the return electrode by the electrosurgical unit

Electrosurgical units are equipped with various safety systems to ensure the correct use of the return electrode. To best use these safety systems:

- Only use electrosurgical units which are listed as suitable in the declaration of conformity of the return electrodes.
- Get very familiar with the safety systems of the electrosurgical unit. You can find information about the electrosurgical unit's safety system in the user manual.

OBJ_DOKU-187952-003.fm Seite 9 Montag, 14. April 2014 10:24 10

OBJ_DOKU-187952-003.fm Seite 10 Montag, 14. April 2014 10:24 10

Manufacturer:

ERBE Elektromedizin GmbH
Waldhörnlestr. 17
72072 Tübingen, Germany
Tel. +49 7071 755 0
Fax +49 7071 755 179
EMail: info@erbe-med.com
www.erbe-med.com

Distributed by (USA Territory):

ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067
Customer Support: 800 778 ERBE (3723)
Tel. (770) 955 4400
Fax (777) 955 2577
EMail: sales@erbe-usa.com
www.erbe-usa.com

CE 0124

© ERBE Elektromedizin GmbH

30193-083 02.14

ERBE